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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/730,878

12/09/2003

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1023-334US01

4796

28863 7590 12/09/2009
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EXAMINER

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ART UNIT

PAPER NUMBER

3762

NOTIFICATION DATE

DELIVERY MODE

12/09/2009

ELECTRONIC

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**BEFORE THE BOARD OF PATENT APPEALS
AND INTERFERENCES**

Application Number: 10/730,878
Filing Date: December 09, 2003
Appellant(s): SINGHAL ET AL.

Jessica H. Kwak
For Appellant

EXAMINER'S ANSWER

This is in response to the appeal brief filed 9/14/2009 appealing from the Office action mailed 4/1/2009.

(1) Real Party in Interest

A statement identifying by name the real party in interest is contained in the brief.

(2) Related Appeals and Interferences

The examiner is not aware of any related appeals, interferences, or judicial proceedings which will directly affect or be directly affected by or have a bearing on the Board's decision in the pending appeal.

(3) Status of Claims

The statement of the status of claims contained in the brief is correct.

(4) Status of Amendments After Final

The appellant's statement of the status of amendments after final rejection contained in the brief is correct.

(5) Summary of Claimed Subject Matter

The summary of claimed subject matter contained in the brief is correct.

(6) Grounds of Rejection to be Reviewed on Appeal

The appellant's statement of the grounds of rejection to be reviewed on appeal is correct.

(7) Claims Appendix

The copy of the appealed claims contained in the Appendix to the brief is correct.

(8) Evidence Relied Upon

6,358,281	Berrang et al.	3-2002
6,112,120	Correas	8-2000

(9) Grounds of Rejection

The following ground(s) of rejection are applicable to the appealed claims:

The rejection of claim 1 under 35 U.S.C. 102(a/e) in view of Berrang:

Claim	Limitation	Disclosure in Berrang (US 6,358,281)
1	An implantable medical device comprising:	Berrang's device is shown generally in Figure 1.
	At least two interconnected modules, each of the modules comprising a respective one of at least two housings to house the respective modules; and	Berrang shows two interconnected modules as elements 18 and 21 in Figure 2, and the housings are the material directly surrounding the modules, such as elements 24, 20, 25, and 23.
	An overmold that at least partially encapsulates each of the housings and is at least partially flexible to allow relative motion between the modules,	Berrang discloses an overmold encapsulating each of the housings at column 9, lines 51-62 and column 11, line 55 to column 12, line 25; element 6; and the disclosed gold and titanium, platinum, silicone, and/or any combination of these that coat the device.
	The overmold comprising a lead connection module configured to accept an external lead,	Berrang shows a "lead connection module" as element 6 in Figure 1 because this is where the lead (16) connects to the rest of the device.
	Wherein the external lead is separable from the lead connection module and	The lead is necessarily "separable" from the lead connection module by, e.g., wire cutters because the materials from which they are constructed are necessarily capable of being cut by such a tool (col. 11, lines 3-27).
	Wherein the lead connection module comprises a feed-through wire that electrically couples to the external lead.	The lead connection module (6) necessarily includes a feed-through wire that electrically couples to the external lead because the external lead stimulates using the circuitry and power source (abstract).

The alternative and additional rejection of claim 1 under 35 U.S.C. 103(a) in view of Berrang and Correas:

Claim	Limitation	Disclosure in Berrang	Disclosure in Correas
1	An implantable medical device comprising:	Berrang's device is shown generally in Figure 1.	

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	At least two interconnected modules, each of the modules comprising a respective one of at least two housings to house the respective modules; and	Berrang shows two interconnected modules as elements 18 and 21 in Figure 2, and the housings are the material directly surrounding the modules, such as elements 24, 20, 25, and 23.	
	An overmold that at least partially encapsulates each of the housings and is at least partially flexible to allow relative motion between the modules,	Berrang discloses an overmold encapsulating each of the housings at column 9, lines 51-62 and column 11, line 55 to column 12, line 25; element 6; and the disclosed gold and titanium, platinum, silicone, and/or any combination of these that coat the device.	
	The overmold comprising a lead connection module configured to accept an external lead,	Berrang shows a "lead connection module" as element 6 in Figure 1 because this is where the lead (16) connects to the rest of the device.	
	Wherein the external lead is separable from the lead connection module and		Correas teaches a separable and re-attachable lead at column 1, lines 58-62.
	Wherein the lead connection module comprises a feed-through wire that electrically couples to the external lead.	The lead connection module (6) necessarily includes a feed-through wire that electrically couples to the external lead because the external lead stimulates using the circuitry and power source (abstract).	

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.

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(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 1-5, 8-10, 12-13, 15, and 19-21 are rejected under 35 U.S.C. 102(a/e) as being unpatentable over Berrang et al. (US 6,358,281, hereinafter "Berrang"), or in the alternative, under 103(a) over Berrang in view of Correias (US 6,112,120, hereinafter "Correias").

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In regards to claims 1 and 9, Berrang discloses an implantable device comprising at least two interconnected modules (Fig. 2, elements 18 and 21, and the material directly surrounding elements 18 and 21, such as 24, 20, 25, and 23), each having a housing (24, 20, 25, and 23); and an overmold encapsulating each of the housings (col. 9, lines 51-62 and col. 11, line 55-col. 12, line 25; element 6; and the disclosed gold and titanium, platinum, silicone, and/or any combination of these) comprising a first material and a second material (the disclosed gold and titanium, platinum, silicone, and/or any combination of these; col. 9, lines 51-62; and element 6) one of which is at least partially flexible to allow relative motion between the modules (element 6 and col. 9, lines 51-62) and comprising a lead connection module (Fig. 1, element 6) configured to accept an external lead (16), the module (6) being embedded within the overmold (because it too is coated with the gold and silicone disclosed at col. 9, lines 51-62), and the module (6) inherently comprises at least one feed-through wire that connects the lead (16) to the power source and control electronics housed within the other two modules (depicted in element 6 in Fig. 2, but lacking a reference numeral). Please note an alternate interpretation wherein electronic module (21) is housed by support disc (33) and battery (18) inherently comprises its own housing because the battery is a lithium ion or nickel metal hydride-type (col. 12, line 55). These batteries contain liquid electrolytes, necessitating a housing. Berrang does not expressly disclose that the lead (16) is “separable from the lead connection module.” However, the lead is constructed of platinum and an inert polymer (col. 11, lines 3-27), which is inherently “separable from the lead connection module” by use of, e.g., wire cutters. In the alternative, Correias

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teaches a cochlear implant system (col. 1, line 16) having a lead that is manually separable and re-attachable to a lead connection module to provide the predictable result of allowing convenient immobilization of a lead on a generator by a surgeon without risk of inopportune disconnection (col. 1, lines 58-62). Therefore, it would have been obvious to one having ordinary skill in the art at the time the invention was made to modify Berrang's invention by providing a lead that is manually separable and re-attachable to a lead connection module to provide the predictable result of allowing convenient immobilization of a lead on a generator by a surgeon without risk of inopportune disconnection.

In regards to claim 2, at least one module contains electronic components (21).

In regards to claims 3 and 13, the overmold comprises a first material and a second material (col. 9, lines 51-62 and col. 12, line 8) and the lead connection module is embedded within the first material (because the lead conductors must pass through all coating materials (the epoxy, gold, palladium, titanium, and silicone of col. 9, lines 51-62 and col. 12, line 20) to reach the outside of the device, the lead connection module is "embedded in" the "first material"). This connection module comprises the conductors that connect 16 with the internal electronics 21.

In regards to claims 4 and 10, the first material is non-elastomeric (gold).

In regards to claim 5, the device includes at least one feed-through wire (col. 11, line 3).

In regards to claim 8, the maximum thickness is between 4 and 8 millimeters (col. 10, line 9).

In regards to claim 12, the second material is silicone (col. 12, line 25).

In regards to claim 15, the modules are horizontally distributed and separately encapsulated by the overmold (Fig. 2).

In regards to claims 19 and 20, the at least one of the modules/the control module is hermetic via the overmold (col. 12, line 18; with respect to the outside of the device). In the alternative, Berrang discloses the claimed invention but does not disclose expressly the hermetic control electronics housing. It would have been an obvious matter of design choice to a person of ordinary skill in the art to modify the control module encapsulation as taught by Berrang with the individual hermetic seal because applicant has not disclosed that individual hermetic seals provides an advantage, is used for a particular purpose, or solves a stated problem. One of ordinary skill in the art, furthermore, would have expected Applicant's invention to perform equally well with the implant as taught by Berrang because both systems hermetically seal the components from the body (col. 11, lines 55-67). Therefore, it would have been an obvious matter of design choice to modify Berrang's invention to obtain the invention as specified in the claims.

In regards to claim 21, the overmold partially encapsulates each of the housings (in this case, the "overmold" is considered to be the epoxy (col. 11, lines 60-66) and the bridge 6, i.e., does not include the gold and/or silicone coating).

Claims 6, 7, and 14 are rejected under 35 U.S.C. 103(a) as being unpatentable over Berrang in view of Correias. Berrang discloses the essential features of the claimed invention except for an isodiametric lead or tool-less mechanical connection.

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Correas teaches providing implantable devices with isodiametric lead connection modules (Fig. 1) to allow the use of conventional leads and to provide tool-less lead securing (Figs. 5 and 6) to provide the predictable result of a simple implantation that requires few implantation implements. Therefore, it would have been obvious to one having ordinary skill in the art at the time the invention was made to modify Berrang's invention by providing an isodiametric lead connection module to allow the use of conventional leads and to provide tool-less lead securing to provide the predictable result of a simple implantation that requires few implantation implements.

(10) Response to Argument

REJECTION UNDER 35 U.S.C. § 102(A/E) OVER BERRANG OR, IN THE ALTERNATIVE, UNDER 35 U.S.C. § 103(A) OVER BERRANG IN VIEW OF CORREAS

CLAIMS 1-5, 8-10, 12, 13, 15, 20, AND 21

Appellant argued, under the 102(a/e) rationale, that the lead of the Berrang device is not necessarily "separable" from the bridge by any means including, e.g., wire cutters because cutting the lead would result in a portion of the lead remaining within element 6. However, nothing in the claim language precludes this result. The claim does not require the entire lead to be separable nor does the claim preclude the consideration of only the portion of the conductor distal to element 6 to be part of the "external lead." In other words, the claim language allows any portion of the conductor within element 6 to not be considered part of the claimed "external lead." In fact, the examiner has indicated that this portion of the conductor within element 6 is the claimed "feed through," as discussed in the rejection above and the remarks below.

Appellant further argued that cutting this external lead from the lead connection module would render the device inoperable because it cannot be replaced, and that, if a proposed modification would render the device unsatisfactory for its intended purpose, there is no suggestion or motivation to make the proposed modification. However, the claim language does not require replace-ability, and the “modification” to which applicant refers pertains to section 103 and not 102. The Examiner does not propose a “modification” under 103, but merely the necessary property of the lead’s ability to be cut or separated. No modification is proposed under the 102 rationale.

Appellant argued, under the 103 rationale, that avoiding the “risk of inopportune disconnection” is not proper motivation to apply the teaching of Correias because Berrang already provides this function as the system is unitary. However, the full motivational statement provided in the rejection was “allowing convenient immobilization of a lead on a generator by a surgeon without risk of inopportune disconnection.” This feature of allowing immobilization by a surgeon (as opposed to a unitary structure) provides such advantages (as would be recognized by an artisan in the field) as: allowing the lead to be manipulated to the desired location and then immobilized on the generator to avoid the problems of the bulky device getting in the way during the implantation procedure and allowing for later replacement of the device if needed while maintaining the lead in the body so as not to disrupt the tissue in-growth around the lead.

Appellant further argued that Berrang fails to disclose a “feed-through wire” as claimed because nothing in Berrang indicates the existence of separate feed-through

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wires that electrically couple the lead to the internal electronics. Appellant further argued that nothing in Berrang indicates that the lead is connected to the electronics or battery. As described at, e.g., claim 1, Berrang clearly describes how the electrodes are connected to the internal circuitry. In regards to the alleged lack of a "separate feed-through wire," nothing in the claim language requires the feed-through wire to be "separate." The claimed "feed-through wire" is merely the portion of the conductor that necessarily connects the external electrodes to the internal circuitry within element 6.

Appellant further argued that Berrang lacks disclosure of " housings " for each of the modules because the portions cited by the Examiner serve other purposes and do not completely encapsulate the modules. However, the fact that the elements serve other purposes (e.g., "providing a mounting surface for a piezoceramics actuator") does not obviate the fact that they do at least partially surround (or "house") the modules. The Examiner's broadest reasonable interpretation of "housing" does not require total encapsulation, but only an element that at least partially contains or covers. Furthermore, regardless of whether any single one of Berrang's elements "house" the modules, Figure 2 clearly shows that a combination of elements completely surrounds each of the modules 18 and 21, and thus provides a "housing."

CLAIM 19

Appellant argued that claim 19 is not obvious in view of Berrang because the Examiner has failed to show that individual hermetic housings are a matter of "design choice," even though Berrang discloses that the housing, as a whole, is hermetic.

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Appellant further indicated that *In re Kuhle* cited the “design choice” rationale, but pertained to rearrangement of parts. However, that is precisely the case in this instance. The Examiner asserted that rearranging the hermetic seal to house each of the modules individually instead of the housing as a whole would have been an obvious matter of design choice because both configurations predictably prevent substances from entering or escaping the system, and would be a mere rearrangement of the housing to house the modules individually instead of the entire system. Further, duplicating hermetic seals by, e.g., coating the individual modules as well as the device as a whole would provide the predictable result of added security of the seal.

REJECTION OF CLAIMS 6, 7, AND 14 UNDER 35 U.S.C. § 103(A) OVER BERRANG IN VIEW OF CORREAS

CLAIM 6

Appellant further argued that there is no reason to modify Berrang to provide a mechanical lead securing mechanism because Berrang's lead is already secured to the bridge. However, Berrang is modified in view of Correas to provide a removable lead that is capable of reconnection, as detailed with regards to claim 1 (from which claim 6 depends). The Examiner maintains that making this connection with a mechanical lead securing mechanism would have been *prima facie* obvious, as detailed in the rejection.

CLAIM 7

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Appellant further argued that there is no reason to modify Berrang to provide a tool-less mechanical lead securing mechanism because Berrang's lead is already secured to the bridge. However, Berrang is modified in view of Correias to provide a removable lead that is capable of reconnection, as detailed with regards to claim 1 (from which claim 7 depends). The Examiner maintains that making this connection with a tool-less mechanical lead securing mechanism would have been prima facie obvious, as detailed in the rejection.

CLAIM 14

Claim 14 is argued by Appellant on the same grounds as claim 9.

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(11) Related Proceeding(s) Appendix

No decision rendered by a court or the Board is identified by the examiner in the Related Appeals and Interferences section of this examiner's answer.

For the above reasons, it is believed that the rejections should be sustained.

Respectfully submitted,

/Michael Kahelin/

Examiner, Art Unit 3762

Conferees:

/George R Evanisko/

Primary Examiner, Art Unit 3762

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